



1.0 PURPOSE

This procedure describes the process that biospecimen source sites (BSS's) follow to receive collection kits from the Comprehensive Biospecimen Resource (CBR) and the process the Biospecimen Source Sites (BSS) use to package biospecimens and ship them to the CBR, the Laboratory Data Analysis Coordinating Center (LDACC), or other institution.

2.0 SCOPE

This procedure applies to all of the organizations involved in the migration of biospecimens, specifically: the CBR, Brain Bank, and the participating Biospecimen Source Sites (BSSs).

3.0 RESPONSIBILITY

- 3.1 **Biospecimen Source Site (BSS):** They will collect and ship biospecimens to the appropriate processing/analysis facility.
- 3.2 **Comprehensive Biospecimen Resource (CBR):** Will manage the preparation and distribution of the shipping kits and receipt of the Aqua Kit specimen collection.
- 3.3 **Study Management Group (Project Subcontractor):** Will train the BSSs on the type of biospecimens to be collected and their transportation requirements, e.g., shipping temperature and International Air and Transportation Association (IATA) regulation.
- 3.4 **Brain Bank (BB):** They will receive all brain and hair specimens from the BSSs.
- 3.5 **Laboratory Data Analysis and Coordinating Center (LDACC):** They will receive the blood and skin samples from the BSSs.

4.0 DEFINITIONS

- 4.1 **BB** – Brain Bank. Receives all brain and hair specimens.
- 4.2 **Bio4D** – Computer system used by BSSs to enter collection and shipping information at the CBR.
- 4.3 **BSS** – Biospecimen source site. An institution contracted to perform tissue and data procurement.
- 4.4 **CBR** – Comprehensive Biospecimen Resource.
- 4.5 **CDR** – Comprehensive Data Resource.
- 4.6 **CRF** – Case report form. Paper form used to collect project related data.
- 4.7 **GTEx** – Genotype-Tissue Expression project.
- 4.8 **IATA** – International Air Transport Association. The oversight authority for the airline industry.
- 4.9 **LDACC** – The Laboratory Data Analysis and Coordinating Center (LDACC).
- 4.10 **PDF** – portable document format.
- 4.11 **SOP** – standard operating procedure.

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4.12 **TCDF** – tissue collection data form.

5.0 ENVIRONMENTAL HEALTH & SAFETY

5.1 Persons packaging and/or signing transport documents must be trained and/or certified to ship the appropriate hazard class according to International Air Transport Association (IATA)/International Civil Aviation Organization (ICAO) regulations.

5.1.1 Training may be conducted through the BSS or offered through the Study Management Group (Project Subcontractor).

5.1.2 Verification of training materials, testing and certification must be provided to the Study Management Group team to certify all staff involved with shipping procedures.

5.2 Persons handling the blood collection tubes or PAXgene[®] tissue containers should be aware of the hazards associated with the chemicals and how to handle an accidental spill or exposure by reviewing the Material Safety Data Sheets. Latex or nitrile rubber gloves are required for persons directly handling the PAXgene[®] tissue containers.

5.3 Appropriate personal protective equipment should be worn at all times to include but not limited to:

- Gown or lab coat;
- Hair bonnet, mask, and shoe covers, per institutional requirements;
- Latex or nitrile rubber gloves.

6.0 MATERIALS/EQUIPMENT

6.1 caHUB/GTE_x Blood & Skin Biopsies Collection (the yellow kit).

6.2 caHUB/GTE_x Whole Brain, Brain Stem and Hair Collection (the green kit).

6.3 caHUB/GTE_x PAXgene[®] Tissue Fixative/Stabilizer (the aqua kit).

7.0 PROCEDURE

7.1 The procedural flow for kit receipt, verification, and shipping is outlined in **GTE_x Specimen Collection Supplies and Shipping Kit Process Flow (OP-0001-P1)**.

Kit Supplies to the BSSs

7.2 The CBR will provide the following color-coded kits to each BSS: caHUB/GTE_x Blood & Skin Biopsies Collection shipped to the LDACC (yellow kit); caHUB/GTE_x Whole Brain,



Brain Stem and Hair Collection shipped to the BB (green kit); and caHUB/GTE_x PAXgene[®] Tissue Fixative/Stabilizer Collection to the CBR (aqua kit).

- 7.3 The BSS verifies the contents of routine kit shipments against the appropriate checklist, either the **GTE_x Kit Discrepancy Checklist for Routine Overpack for Postmortem Collections (OP-0001-F2)** or the **GTE_x Kit Discrepancy Checklist for Routine Overpack for Surgical Collections (OP-0001-F4)**.

Collection Event & Packing

- 7.4 Once a donor has been identified, retrieve the appropriate kit from the storage location.
- 7.5 If a brain is collected (not applicable for surgical collections), an automatic alert to the BB by EMAIL will be generated by the Shipping Vendor as listed in the instructions in the Alert of Pending Collection subsection of the **Work Instruction for Green Kit Receipt and Shipping (OP-0001-W2)**. A phone call must also be placed by the procurement team to alert the BB hotline of a shipment; which in turn alerts the on-call staff.
- 7.6 Collect the specimen(s) using the **GTE_x Tissue Procurement SOP (PR-0004)**.
- 7.7 Following the **GTE_x Bio4D BSS User Guide**, print the **GTE_x Tissue Data Collection Form (from Bio4D)** (or other local traveling manifest) that will be included in the shipped aqua kits. For the yellow and green kits use the pre-printed TCDFs that are provided in the Routine Overpacks.
- 7.8 Prepare the collected specimen(s) for shipment using the appropriate color coded work instruction: use the **GTE_x Work Instruction for Yellow Kit Receipt and Shipping (OP-0001-W1)** for the yellow kit; the **GTE_x Work Instruction for Green Kit Receipt and Shipping (OP-0001-W2)** for the green kit; or the **GTE_x Work Instruction for Aqua Kit Receipt and Shipping (OP-0001-W3)** for the aqua kit.

Kit Shipping

- 7.9 Manually alert the LDACC and CBR of the collection shipment using the appropriate color coded work instruction: for the aqua kit use the Alert of Pending Collection subsection in the **GTE_x Work Instruction for Aqua Kit Receipt and Shipping (OP-0001-W1)**; and for the yellow kit use the Alert of Pending Collection subsection in the **GTE_x Work Instruction for Yellow Kit Receipt and Shipping (OP-0001-W3)**.

8.0 REFERENCES



- 8.1 GTEx Tissue Procurement SOP, PR-0004
- 8.2 Work Instruction for caHUB Data Entry at BSS, IT-0001-W1
- 8.3 Work Instruction for Shipping Receipt at Processing Facility, IT-0001-W2

9.0 ATTACHMENTS

- 9.1 GTEx Kit Discrepancy Checklist for Routine Overpack for Postmortem Collections, OP-0001-F2
- 9.2 GTEx Kit Discrepancy Checklist for Transport Media, OP-0001-F3
- 9.3 GTEx Kit Discrepancy Checklist for Routine Overpack - Surgical Collections, OP-0001-F4
- 9.4 GTEx Work Instruction for Yellow Kit Receipt and Shipping, OP-0001-W1
- 9.5 GTEx Discrepancy Checklist for Yellow Kit, OP-0001-W1-F1
- 9.6 GTEx Work Instruction for Green Kit Receipt and Shipping, OP-0001-W2
- 9.7 GTEx Discrepancy Checklist for Green Kit, OP-0001-W2-F1
- 9.8 GTEx Work Instruction for Aqua Kit Receipt and Shipping, OP-0001-W3
- 9.9 GTEx Discrepancy Checklist for Aqua Kit - Surgical, OP-0001-W3-F1
- 9.10 GTEx Discrepancy Checklist for Aqua Kit - Postmortem, OP-0001-W3-F2
- 9.11 GTEx Specimen Collection Supplies and Shipping Kit Process Flow, OP-0001-P1



APPROVALS

NAME / TITLE

NAME / TITLE	

INITIATION/REVISION HISTORY

REV #

DESCRIPTION OF CHANGE

AUTHOR

EFFECTIVE DATE

REV #	DESCRIPTION OF CHANGE	AUTHOR	EFFECTIVE DATE